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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Application No. | | Applicant(s) | | | | | |
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| Office Action Summary | | 10/672,149 | | CHAN ET AL. | | | | | |
| | | Examiner | | Art Unit | | | | | |
| | | CYNTHIA B | WILDER | 1637 | | | | | |
| The MAILING DA Period for Reply | The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | | | |
| A SHORTENED STATU WHICHEVER IS LONG - Extensions of time may be avai after SIX (6) MONTHS from the If NO period for reply is specific - Failure to reply within the set of | ITORY PERIOD FOR REFER, FROM THE MAILING lable under the provisions of 37 CFR mailing date of this communication. It is above, the maximum statutory period for reply will, by state than three months after the massee 37 CFR 1.704(b). | DATE OF THIS 1.136(a). In no event od will apply and will e tute, cause the applica | COMMUNICATION, however, may a reply be timexpire SIX (6) MONTHS from the become ABANDONE | N. nely filed the mailing date of this (0) (35 U.S.C. § 133). | · | | | | |
| Status | | | | | | | | | |
| 2a)⊠ This action is FIN . 3)□ Since this applica | mmunication(s) filed on <u>04</u> AL . 2b) ☐ TI tion is in condition for allov nce with the practice unde | his action is nor wance except fo | r formal matters, pro | | e merits is | | | | |
| Disposition of Claims | | | | | | | | | |
| 4a) Of the above of 5) ☐ Claim(s) is 6) ☑ Claim(s) <u>26, 29-3</u> ; 7) ☐ Claim(s) is | <u>8</u> is/are rejected. | rawn from cons | | | | | | | |
| _ | | · | | | | | | | |
| 10) The drawing(s) file Applicant may not re Replacement drawi | s objected to by the Exami d on is/are: a) a equest that any objection to the ng sheet(s) including the corre ation is objected to by the | accepted or b) he drawing(s) be rection is required | held in abeyance. See if the drawing(s) is obj | e 37 CFR 1.85(a). ected to. See 37 C | | | | | |
| Priority under 35 U.S.C. § | 119 | | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | | |
| Attachment(s) 1) Notice of References Cited (2) Notice of Draftsperson's Pal (3) Information Disclosure State (Paper No(s)/Mail Date | ent Drawing Review (PTO-948) | _ |) | ate | | | | | |

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DETAILED ACTION

1. Applicant's amendment filed May 5, 2008 is acknowledged and has been

entered. Claims 26, 31-33 have been amended. Claims 1-25, 27, 28 have been

canceled. Claims 35-38 have been added. Claims 26, 29-38 are pending. All of the

arguments have been thoroughly reviewed and considered but are deemed moot in

view of the new grounds of rejections necessitated by applicant's amendment of the

claims. Any rejection not reiterated in this action has been withdrawn as being obviated

by the amendment of the claims.

This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can

be found in a prior Office action.

Previous Rejections

3. The prior art rejections under 35 USC 112 second paragraph are withdrawn in

view of Applicant's amendment of the claims. The prior art rejection under 35 USC

103(a) as being unpatentable over Shipwash in view of Shipway et al and further in view

of Williams et al is withdrawn in view of the new grounds of rejections necessitated by

Applicant's amendment.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S

AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 112: New Matter

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 26 and 29-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation at the step (d); "a hot spot having a three dimensional porous structure, the hot spot being stationary within the second channel and comprising a plurality of cross-linked nanoparticles aggregates affixed within the hot spot within the second channel, wherein the hot spot enhances a Raman signal of the single nucleotide", is not supported by the specification as originally filed. The limitation suggests that a hot spot is a separate entity of the apparatus and is separate from the cross-linked nanoparticles aggregates. However, the specification teaches at paragraph 0025 of the published application US 2004/0110208 that "the nanoparticles 111 may be treated to form "hot spots". The specification teaches at paragraph 0037 that "formation of "hot spots" for SERS, SERRS and/or CARS detection may be associated with particular aggregates of nanoparticles. Paragraph 0102 further teaches that "[Th]e nanoparticles 111 may be cross-linked to form "hot spots" for Raman detection". By passing the nucleotides 110 through the nanoparticles 111 hot spots, the sensitivity of Raman detection may be increased by many orders of magnitude". The

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teachings of the specification hence suggest that the cross-linking of the nanoparticles aggregates form hot spots and thus hot spots do not form nanoparticle aggregates.

There is no suggesting anywhere of any structures of the hot spots (three dimensional or otherwise). The cited paragraph 0025 as noted by Applicant does not disclose wherein the "hot spots" are three-dimensional or porous structure". Likewise, there is no teachings anywhere in the specification which would suggest that the nanoparticles which form "hot spots" to be porous or three-dimensional. In fact the nanoparticles are metal compounds which are not porous. Figure 1 does not support this limitation either. While the Examiner agrees that the Figure 1 shows a plurality of nanoparticles packed or immobilized (stationary) within one of the channels, there is nothing in the Figure 1 which clearly identifies which portion of the packed nanopaticles are hot spots. Thus, given the lack of support in the instant specification for the claimed invention as currently written, the specification would not have suggested to the skilled artisan that Applicant was in possession of the claimed invention as of the filing date.

Claim Rejections - 35 USC § 112

- 6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 7. Claims 26 and 29-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The claims 26 and 29-38 are confusing in the claim 26 at step (d) at "a hot spot having a three-dimensional porous structure..." because it is unclear how the "hot spot" modifies the structure of the apparatus. A hot spot would not be readily apparent in the apparatus until the apparatus has function in a manner to display a Raman signal, which would be enhanced or brighter based on the presence of hot spots

Claim interpretation

8. The instant claims are drawn to an apparatus for detecting a single nucleotide by Raman spectroscopy comprising (a) a reaction chamber, (b) a first channel in fluid communication with the reaction chamber; a second channel in fluid communication with the first channel; a hot spot having a three dimensional porous structure, the hot spot being stationary within the second channel and comprising a plurality of crosslinked nanoparticles aggregates affixed within the hot spot within the second channel.; and a Raman detector operably coupled to the second channel. MPEP 2114 states, "While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d, 1429, 1431-32 (Fed. Cir. 1997)." This section of the MPEP further states, A claim containing 'a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)". Finally, section 2114 of the MPEP

states, "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claimed. In this case, such limitations as "for detecting a single nucleotide by Raman spectroscopy", to detect the single nucleotide" and "positioned to create a field to guide the single nucleotide from the first channel into the second channel such that the nucleotide pass through the hot spot" are intended use limitations of that apparatus that do not impart a structural feature of the apparatus. Additionally, it is noted that the recitation of a exonuclease, and specific nucleotides and the presence of a label does not carry any patentable weight because they do not further limit the structure of the apparatus. Rather, these limitations only describe the features of the contents of the apparatus during its operation.

Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 26, 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash (citation made of record in prior Office action in view of Shipway (citation made of record) and further in view of Nie et al (Science, vol. 275, pages 1102-1106, 1997). Regarding claim 26, Regarding claims 26, Shipwash teaches an apparatus comprising a reaction chamber a first channel in fluid communication with the reaction chamber; a second channel in fluid communication with the first channel; a multiplicity of nanoparticles affixed in the second channel and a detector coupled to the nanoparticle packed channel, wherein said detector is a Raman detector (figure 14 and paragraphs (see paragraphs 0066, 0167, 0174, 0189, 0270, 0395, 0425, Example 15 and claim 38).

Shipwash does not expressly teach wherein the multiplicities of nanoparticles are a plurality of cross-linked nanoparticles aggregates which form a hot spot having a three dimensional porous structure. However, the structure of the hot spot being a three-dimensional porous structure is inherent in the teachings of nanoparticle aggregates as taught by Shipway and Nie et al.

Shipway et al provides a review of nanoparticles arrays on surfaces. Shipway teaches that nanoparticles can be constructed from any charged nanoparticle and an oppositely charged "crosslinker" in an analogous way to the construction of colloid-polymer architectures. Shipway teaches that the "crosslinker" may be anything from a

small molecule to another nanoparticle from a small molecule to another nanoparticle (page 26, first paragraph under the section 2.3.2 in column 1). Shipway teaches when an adsorbate on a rough metal surface is subject to Raman Scattering spectroscopy, very high enhancements over a flat surface are observed. Shipway teaches that Plasmon resonances of nanoparticles aggregates provide an even better excitation frequency for surfaced enhanced Raman scattering. Shipway teaches that there are problems with aggregating nanoparticles in solution; however, Shipway teaches ways to stabilize colloid aggregates in solution. Shipway teaches that nanoparticles can be immobilized so their aggregation state can be carefully controlled. Shipway teaches surface enhanced Raman scattering activity is strongly dependent on the aggregation state of the particle (page 36 and 37, section 4.1.2. and Figure 18).

Nie et al supports the teachings of Shipway. Nie et al teach optical detection and spectroscopy of single molecules and single nanoparticles. Nie et al teach that by coupling single molecule to nanoparticles, they demonstrated that nanometer-sized particles can amplify the spectroscopic signatures of single molecules enormously and that the size dependent properties of nanostructures can be examined at the single particle level (page 1102, second column, lines 3-9). Nie et al further teach the formation of "hot spots" or "hot particles". Nie et al teach that these colloid particles emit bright, strokes-shifted (toward longer wavelengths) light. Nie et al teach that the colloid particles (nanoparticles) may be immobilized on polylysine-coated glass surfaces (page 1102, col. 3, first full paragraph). Nie et al further teach wherein the activated colloid particles contains large cluster of particles, which are believed to be the most

efficient for Raman enhancements. Nie et al teaches that a fraction of these colloids (nanoparticles) consists of aggregates each containing two to six tightly packed particles (page 1103, col. 1). Nie et al teaches that it is not clear whether aggregation causes the efficient Raman enhancement or if a hot particle happens to be trapped in the aggregates. In either case, Nie et al notes that several lines of evidence indicates that surface-enhanced Raman scattering signal arises from single adsorbed molecules or conjugated molecular aggregates that behave as single molecules (col. 2, page 1103).

In view of the foregoing, one of ordinary skill in the art at the time of the claimed invention would have been motivated to modify the apparatus of Shipwash to encompass a plurality of crosslinked nanoparticle aggregates comprising hot spots as taught by Shipway et al in view of Nie et al for the predictable results of amplifying the spectroscopic signature of single molecule. It would have been further obvious to one having ordinary skill in the art to incorporate a plurality of nanoparticle aggregates comprising hot spots as taught by Shipway et al in view of Nie et al into the apparatus of Shipwash et al, since the presence of the hot spots is in no way dependent on the operation of the other components of the apparatus, the presence of the hot spots within the channel of the apparatus in no way effects the structural features of the apparatus or the function of the apparatus and thus could be used in combination with the other structural components of the apparatus to achieve the predictable results of detecting a single nucleotide by Raman spectroscopy as suggested by Nie et al. The combination of prior arts is *prima facie* obvious.

Regarding claim 29 and 30, Shipwash teaches the apparatus of claim 26, wherein the first channel is a microfluidic channel and the second channel is a nanochannel or microchannel (see figure 14 and paragraph 0210 and 0425).

Regarding claim 31 and 32, Shipway teaches wherein the aggregates comprise at least 2 to 4 nanoparticles (see Figure 18 and legend).

Regarding claim 33, Shipway teaches wherein the nanoparticles comprising the aggregates are silver and are about 35 nm in diameter (see page 37, col. 1, first full paragraph and Figure 18). Nie et al also teaches wherein the nanoparticles are about 35 nm in size at a typical concentration of `10¹¹ particles/ml (page 1102, 3rd column).

Regarding claim 34, Shipwash teaches the apparatus of claim 26, wherein the plurality of cross-linked nanoparticles affixed within the second channel are throughout a cross sectional area of the second channel and the Raman detector is adapted to detect said Raman signal (Figure 14).

10. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash in view of Shipway and Nie et al as previously applied above in view of Ulmer et al (5674743) and further in view of Vo-Dihn (5306403). Regarding claims 35-37, Shipwash et al in view of Shipway and further in view of Nie et al teach an apparatus capable of detecting a single nucleotide by Raman spectroscopy comprising a reaction chamber, a first channel in fluid communications with the reaction chamber; a second channel in fluid communications with the first channel; a plurality of nanoparticle

aggregates comprising a three-dimensional porous structure and comprising a hot spot. and a Raman detector operably coupled to the second channel.

Shipwash et al in view of Shipway and further in view of Nie et al do not expressly teach wherein the reaction chamber comprises an exonuclease (claim 35), or wherein the single nucleotide is an unlabeled nucleotide or wherein the single nucleotide is a single Raman labeled nucleotide.

Ulmer teaches an apparatus (see abstract and Figure 7) comprising: a reaction chamber comprising an exonuclease (see col. 23, line 1 to col. 24, line 26, Figure 7 and col. 26, line 33 to col. 28, line 67), an attachment channel in fluid communication with the reaction chamber and comprising a nucleotide-nanoparticle complex of a nanoparticle and a nucleotide wherein the nucleotide is covalently attached to the nanoparticle (see col. 23, line 1 to col. 24, line 26, Figure 7 and col. 26, line 33 to col. 28, line 67); a flow-through cell in fluid communication with the attachment channel and a detection unit operably coupled to the flow through cell (see col. 30, line 10 to col. 32, line 11 and col. 39, lines 14-25). Ulmer et al additionally teaches wherein the nucleotides are single unlabeled nucleotides (see col. 30, lines 50-57 and col. 14, lines 10-20).

Ulmer does not teach wherein the single nucleotide is a single Raman labeled nucleotide.

Vo-Dihn teaches detection of DAN sequencing products using Raman spectroscopy and SERS (see the abstract and col. 4, lines 16-40). Vo-Dihn et al

teaches Raman tags in the channel with binds to the nucleotide during DNA sequencing (see Example 1).

In view of the foregoing, it would have been prima facie obvious to one ordinary skill in the art at the time of the claimed invention that the reagents of Ulmer et al and Vo-Dihn et al could be predictably used in the apparatus of Shipwash in view of Shipway and further in view of Nie et al, since the reagents in no way effect the operation of the apparatus of Shipwash in view of Shipway and further in view of Nie et al. Likewise, it would have been obvious to one of ordinary skill in the art that the reagents, such as the single unlabeled nucleotide could be used in the apparatus of Shipwash in view of Shipway and further in view of Nie et al since Shipway, like Ulmer et al is concern with nucleic acid sequencing. One of ordinary skill in the art would have been motivated to use Raman spectroscopic techniques as taught by Shipwash in view of Shipway and Nie et al and further in view of Vo-Dihn et al since Ulmer states a desire to detect noting, "The detection station comprises a source of radiation which preferably is a high repetition rate pulsed laser for stimulating natural fluorescence from the nucleotides, a detection system for detection of fluorescence from the nucleotides, and means for identifying the nucleotide from the detected fluorescence (see col. 15, lines 18-25). Likewise, Shipwash, Shipway, Nie et al and Vo-Dihn et al recognize the benefits of SERS for detecting single molecules. Vo-Dihn et al additionally recognizes the usefulness of SERS for detection of DNA sequencing products. Vo-Dihn notes "The sensitivity of the Raman spectroscopic components is enhanced by surface enhancement, this producing a surface enhanced Raman spectroscopy system for DNA

sequencing" (see col. 3, lines 30-34). Vo-Dihn further teaches that Raman spectroscopy has excellent specificity (see col. 4, lines 6-9). Thus, one having ordinary skill in the art would have been motivated to use SERS detection methods as taught by Shipwash, Shipway, Nie and Vo-Dihn for the obvious benefit of achieving desired sensitivity and specificity in detection of nucleotides.

11. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash in view of Shipway and Nie et al as previously applied above in view of Williams et al (citation made of record in prior Office action). Regarding claim 38, Shipwash et al in view of Shipway and further in view of Nie et al teach an apparatus capable of detecting a single nucleotide by Raman spectroscopy comprising a reaction chamber, a first channel in fluid communications with the reaction chamber; a second channel in fluid communications with the first channel; a plurality of nanoparticle aggregates comprising a three-dimensional porous structure and comprising a hot spot. and a Raman detector operably coupled to the second channel.

Shipwash in view of Shipway et al and Nie et al do not expressly teach wherein the electrode is adapted to create a field to guide nucleotides from the first channel into the second channel.

Williams et al teach a method and microfluidic system for detecting and sequencing a single molecule, the microfluidic system comprising at least a first energy field source having an energy field transverse to the sample stream, a second energy field source having a second energy field axial to the sample stream. Williams teach

that the traverse field has a pair of electrodes and optionally, the axial field has a hydrostatic pressure differential (0159). Williams teach that the applied fields are electric fields, pressure fields and combinations thereof. Williams state that the fields are variable, thus permitting control of the motion of the nucleotides (0018). Williams teach that the system comprise a flowcell, which comprise channels for the sample stream (0161) and further teaches how the electric field forces control movement from one channel to the next (see 0214, 0217, and 0220-0225).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention to have been motivated to have applied a pair of electrodes to the device of Shipwash in view of Shipway and Nie et al for the benefit of providing a traverse field created by the pair of electrodes to control the motion of the nucleotides through the different channels as taught by Williams et al. One of ordinary skill in the art at the time of the claimed invention would have been further motivated to utilize the electrodes taught by Shipwash in view of Shipway and Nie et al to create a traverse field for the additional benefit of increasing the ability of the device to detect and sequence the target molecules of interest.

Response to Arguments

12. Applicant traverses the rejections on the grounds that the instant invention recites unexpected results (see page 8 and 9 of Applicant's response filed May 5, 2008). The arguments are not found persuasive as neither the claims nor Applicant arguments clearly depict any evidence of unexpected results. The claims as currently written are drawn to an apparatus and not a method comprising structural components.

Applicant is reminded that such limitations as "for detecting a single nucleotide by Raman spectroscopy" is an intended use of the claimed apparatus and does not impart functionality to the structure of the apparatus. MPEP 2114 states, "While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d, 1429, 1431-32 (Fed. Cir. 1997)." This section of the MPEP further states, A claim containing 'a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)". Finally, section 2114 of the MPEP states, "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claimed. MPEP states that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The claims also do not depict the unexpected results asserted by Applicant as the art recognizes the usefulness and predictability of Raman spectroscopy for detecting single molecules and for sequencing DNA molecules in an efficient manner as noted in the cited prior art above. Likewise, MPEP states that "objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value

includes evidence of unexpected results, commercial success, solution of long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). Applicant's arguments are not sufficient to overcome the prior art rejections under 35 USC 103(a).

Conclusion

13. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the

examiner should be directed to CYNTHIA B. WILDER whose telephone number is

(571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

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/cbw/

/GARY BENZION/

Supervisory Patent Examiner, Art Unit 1637